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Therapeutic Goods Administration

FSM is campaigning to ensure that only devices with proven evidence of safety and effectiveness should be offered to the Australian public.

FSM wrote to the National Manager, Therapeutic Goods Administration (TGA) with a series of questions relating to some questionable pathology devices. The Manager confirmed that there were no "Live Blood Analysis (LBA)" devices listed. He also stated that the TGA had reviewed a number of electrodermal devices and, while no regulatory action was required for some of them, other sponsors had been required to modify their entry. Two goods, the BICOM and the Zyto Elite, are under review.

The letter also stated: *"We will consider information from any source about therapeutic goods supplied in Australia or exported from Australia whether or not they are included in the ARTG. We are particularly keen to hear about potential safety issues and will always give these priority."*

FSM is aware that hundreds of pseudoscience-based health practitioners actually use these pathology tests. In this light the [response](#) by the TGA is very disappointing.

FSM understands that:

Fewer than 10% of new 'low risk' entries onto the ARTG (complementary medicines & Class I-IIa devices) are

randomly selected for post-market review. This means that

- More than 90% of new complementary medicine entries are only scrutinised for compatibility with a number of key rules during the online application process;
- There is no pre-market scrutiny of the actual product specification, label, instructions, packaging, advertising or evidence, and;
- Low-risk devices receive virtually no pre-market scrutiny.

Apart from a few yes/no questions aimed at classification, there is only a small list of 'prohibited words' which will stop an online device application going through, and a small 'restricted word' list which will trigger a review. These hurdles are well known and easily circumvented. There is no effective way of stopping a sponsor from applying to put a 'low risk' product that has been removed from the ARTG for any reason, including safety and/or performance, straight back onto the ARTG with the same 90% probability of no review.

FSM is unaware of any sponsor being threatened with prosecution for providing false and/or misleading information in an application.



National Health & Medical Research Council (NH&MRC)

The release of the NHMRC draft information paper on homeopathy represents an important milestone. Homeopathy is a form of 'alternative' medicine for which there is not only no scientific basis, but for which there is very strong evidence of lack of effectiveness.

The [NHMRC draft information paper](#), "*Evidence on the effectiveness of homeopathy for treating health conditions*", concluded that "*the assessment of the evidence from research in humans **does not** show that homeopathy is effective for treating the range of health conditions considered*".

This report generated considerable [media coverage](#) in Australia and overseas.

FSM published [an open letter](#) congratulating Professor Warwick Anderson and his [Homeopathy Working Committee](#), (which, interestingly included members trained in homeopathic medicines), on their thorough and definitive report on the effectiveness of homeopathy. FSM offered complete support for this document and its conclusions. FSM is aware that, in other countries, governments have 'watered down' very specific recommendations about alternative interventions, including homeopathy, and that, in recent years, there has been little evidence demonstrating that governments have the courage to stand up to the vested interests of the well-funded, \$4 billion 'alternative' health industry.

Victorian Government's Better Health Channel

Better Health Channel (BHC) is promoted as a source of "*Health and medical information for consumers, quality assured by the Victorian government*".

FSM is of the opinion that information about the benefits of alternative interventions such as homeopathy and acupuncture (which states that "*research has found that acupuncture may be effective in treating a range of disorders in areas including....*", and lists a wide range of disorders and diseases including digestive, emotional, gynaecological, neurological, respiratory, vascular and smoking cessation) far too often include unproven claims.

[FSM wrote](#) to Dr Pradeep Philip, Secretary, Department of Health (Victoria), requesting changes be made to the BHC website, to reflect current research. FSM also raised concerns about the Government's implied endorsement of inappropriate events listed in the BHC Calendar. FSM received a positive response from Dr Philip, who stated that the *Homeopathy Awareness*

Week event had been removed from their Calendar. He also stated "*The Department of Health is currently undertaking a review of all the complementary and alternative medicine content to ensure that information is up to date with current research. Homeopathy and acupuncture will be included as part of this review*". The review is currently underway with entries for [acupuncture](#), [kinesiology](#) & [Bowen therapies](#) now removed and replaced with the message: "*This web page has recently been removed for review from the Better Health Channel.*"

The entry on [homeopathy](#) is no longer available, and the [chiropractic entry](#) has been reviewed by the RMIT, and claims relating to childhood conditions have been removed.

University news

We are continuing to pressure universities to remove non-evidence based health courses. With a recent push to upgrade Diploma courses in Naturopathy, Homeopathy and other alternative therapies into Bachelor degrees, some universities may put economic imperatives before their duty to the public to graduate evidence-based practitioners. We report below some of the ongoing issues and the relevant interactions with some of the Universities.

Monash University

The Graduate Certificate in Medical Acupuncture (GCMA) course has now been discontinued.

Macquarie University

Macquarie Universities chiropractic degree is in the process of being axed and plans to transfer its chiropractic teachings by 2015.

Visceral manipulation

We have identified a serious issue in the teaching of 'Visceral manipulation' (VM). VM was developed by the French osteopath and physical therapist, Jean-Pierre Barral. It is based on pseudoscientific theories and involves gentle movement of the abdominal and pelvic areas. Barral practitioners say that they can detect "rhythmic motions" from the intestines and other internal organs, which they manipulate to stimulate healing. They claim that manipulation can change the course of many diseases and disorders. VM includes both diagnosis and intervention. Used on both people and animals, it is promoted by a growing number of conventional and alternative health practitioners. VM courses attract substantial professional development hours and this intervention may also be included in university studies.

While VM practitioners are mostly osteopaths, it is also promoted on the websites of physiotherapy, nursing, manual therapy and naturopathic practitioners here and overseas.

Barral's books are still available at Victoria University, RMIT, Southern Cross Universities, University of Western Sydney and Charles Sturt University.

Victoria University

In response to our queries, Victoria University

has confirmed that the visceral component of Osteopathy taught there is not based on Barral's pseudo-scientific theories, but revolves around common conditions which might be amenable to manual treatment (such as constipation, when no other pre-existing pathology is identified). We are pleased that Barral's textbook, which had been a reading requirement for Victoria University's Osteopathic Science 9 (Visceral osteopathy) course, has been removed from their reference list.

According to the Discipline Group Leader - Osteopathic Medicine, College of Health & Biomedicine, Victoria University, "the focus of Osteopathy is treating musculoskeletal problems and associated pain, although osteopaths also have a role in general health promotion and empowering people to take better care of their health".

RMIT University

FSM received responses from Professor Peter Coloe, Pro Vice-Chancellor, Science, Engineering and Health, and Vice-President, RMIT regarding our concerns that RMIT is continuing to teach pseudoscientific interventions such as Applied Kinesiology and Sacro Occipital Therapy, and is promoting 'subluxation' theory. In his latest letter to FSM, Coloe stated that none of their RMIT Chiropractic Program team subscribes to "a monocausal theory of disease" and they do not promote this theory to students. Coloe also stated that 'subluxation' was only used within "the context of historical development of chiropractic during the 19th century".

His letter stated that the team "does not teach paediatric manipulative techniques" and that their course material does not imply that "chiropractic is an appropriate form of therapy for the likes of childhood autism, ADD and organic pathologies in childhood".

Coloe also claimed that the team is not staffed by individuals "who teach and hold some sort of quasi-religious or fundamentalist approach to health care". FSM provided evidence that the private clinic of their former Program Director, (Acting) Discipline of Chiropractic and lecturer at RMIT, a "board certified Paediatric Chiropractor" stated: "many conditions that we often treat

University news ctd...

children for include allergies, asthma, "growing pains", ADD and ADHD".

FSM also referred the RMIT to a 2013 chiropractic curriculum that included the teaching of Applied Kinesiology (AK), Cranial Therapy (CT) and Sacro Occipital Therapy (SOT). RMIT has made no indication that it will change any component of their curriculum. This university also continues to advertise a wide range of pseudo-therapies such as 'energy medicine'.

FSM received a response from the Discipline Leader, Osteopathy, School Health Sciences, who stated that *"the techniques of osteopathy in the cranial field (OCF) are not taught at RMIT, however the historical material that refers to OCF and its model, as well as the evidence in the literature regarding it, are covered in teaching material."*

FSM maintains that, although universities are not expected to be responsible for the actions of their graduates, they are intellectually responsible for teaching material that is likely to be contrary to best health practices. FSM is concerned that many RMIT graduates support practices that either lack credible evidence or are overtly dangerous. FSM sent a report containing images from websites of more than 100 RMIT Chiropractic graduates promoting 'subluxation' theory and/or targeting babies and children.

The well publicised case of a four-month-old

baby, 'adjusted' on six occasions over a five-week period in early 2012, resulting in a fractured vertebra, had been treated by an RMIT trained chiropractor. FSM referred RMIT to this case in a letter to their VC. FSM expresses deep concern that such cases are consequences of pseudoscience teachings. FSM campaigns to prevent chiropractic treatments of babies or children.

Central Queensland University (CQU)

Following a publication in the *Chiropractic Journal of Australia* of an article which made defamatory remarks about FSM, the ethics committee of CQU requested the author, the Head of Department, Chiropractic, to publish a letter of apology. FSM is satisfied with this timely and appropriate response.

The continued offering by so many Australian universities of pseudoscientific courses under the banner of "Health Sciences", is cause for great concern, especially in a climate where funding pressures and university deregulation are likely to combine, tempting more universities to offer "training" in lucrative but discredited practices which, by their very nature, cannot meet the well-known requirements of true scientific research or clinical validation.

Australian Health Practitioner Regulation Agency (AHPRA)

AHPRA Review

Following several letters to AHPRA, FSM met with their legal counsel to discuss a number of issues relating to the self-regulation of alternative medicine courses (in particular Chiropractic and Osteopathy). Our discussion included concerns about pseudoscience based courses which attract Continuing Professional Development hours (such as *"Webster Breech Turning Technique"*, which claims that it can turn breech foetuses in utero).

We were told there is no 'big brother' to monitor the behaviour of the individual Boards, and were advised to write a submission during the next round of consultations.

FSM wrote to The Hon Jillian Skinner MP, Chair, Australian Health Workforce Ministerial Council, Minister for Health, New South Wales, about the proposed Review of the National Registration Program for health practitioners. The letter stated: *"We feel that FSM is well positioned to work with government to improve minimal but effective supervision and regulation*



AHPRA ctd...

of health care in Australia and we would be happy to work with you to achieve those goals".

FSM is delighted with the response of the Minister, confirming that a review is *"expected to be conducted over a nine month period, concluding in March 2015"*.

Testimonials

FSM documented images from one hundred registered practitioner websites using testimonials. This is in breach of the [National Law](#). AHPRA is investigating these practitioners following this alert by FSM.

Chiropractic

An audit committee is currently in the process of reviewing chiropractic courses which attract Continuing Professional Development (CPD) hours. Practice-building courses, such as those

teaching chiropractors how to grow their business by targeting new families, no longer qualify as CPD courses. FSM fully support this move. *Physiotherapy*

In June, FSM met with AHPRA and the Physiotherapy Board in Melbourne. Concerns raised included Osteopathy pseudo-therapies '[craniosacral therapy](#)' ([Upledger](#)) and '[visceral manipulation](#)' ([Barral](#)) courses. In particular, the issue of course providers targeting physiotherapists was raised. The Chair of the Board agreed to discuss these courses with the Australian Physiotherapy Association (APA), whose logo appears on both of the course providers' websites. FSM provided additional information about the courses, including articles from evidence-based osteopaths and a copy of the letter from Victoria University, which has removed these procedures from their curricula and websites.

Private Health Insurance

FSM is campaigning to remove pseudoscience based 'alternative' interventions from being offered by general Health Funds. FSM is of the opinion that individual clients should not pay for those who choose to receive 'alternative' treatments. Unfortunately, with the exception of the Doctors Health Fund, all other Australian health insurers provide coverage for 'alternative' interventions.

Uni Health Insurance

Several Friends have raised concerns about Uni Health Insurance – a new entrant in the market – targeting people in the tertiary education community and their families. Their "Complementary Therapies" advertising includes, such practices as aromatherapy, homeopathy and kinesiology.

FSM [wrote to Uni Health](#) pointing out that the university community values scientific evidence, and urged them to re-consider providing cover for 'alternative' interventions for which there is no evidence of efficacy.

FSM received a disappointing response, which stated: *"Uni Health Insurance is a health insurance fund, not a medical fund"* and that it was their *"responsibility to provide members with access, choice and flexibility in the treatment of*

health related illness or injury, through sustainable products".

Teachers Union Health

FSM [also wrote](#) to Teachers Union Health about their [acupuncture page](#), which claims that it might be useful for a wide range of diseases and disorders, including asthma and addictions. We urged them *"to review the claims made and amend your website to reflect current evidence"* because *"Using acupuncture for conditions where the evidence shows that it works no better than a placebo can delay accurate diagnosis and effective treatment, putting the health of your members at risk."*

The Teachers Union Health (TUH) responded that they will *"review its web site to ensure the information is accurate and consistent with currently available medical information."* FSM is pleased to acknowledge this responsible approach.

FSM is also campaigning for insurers to offer the option in extras for the insured to be able opt out of paying for alternative therapies and therapists.

Pathology



FSM received a positive letter from the Australian Pharmacy Liaison Forum (APLF), an independent coalition representing ten Pharmacy associations, including the Australian Pharmacy Council, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia and the Pharmaceutical Society of Australia. Their letter stated that they supported the FSM/RCPA Pathology Recommendations and that *"each member pharmacy organisation has taken the responsibility to inform and educate their respective members regarding this issue."* FSM regards this as an excellent outcome.

FSM has sent a second letter to the APLF asking about their position on naturopathic clinics located in pharmacies and on the sale of homeopathic remedies. Our submission included two reports, one containing images from 20 pharmacies selling homeopathic remedies and a second report containing images from 50 pharmacies promoting interventions such as Allergy testing (unspecified), Detox, Electrodermal Screening (e.g. Vega), Functional Pathology, Hair Analysis, Heavy Metal Analysis, Homeopathy, Iridology, Kinesiology, Live Blood Analysis, Nail Analysis, Reflexology, Reiki, Stool & Urine Analysis, Tongue Analysis, Tooth Meridian Diagnostics and Zinc Taste Test.

Senator Nick Xenophon, Independent Senator for South Australia, wrote to the Hon Peter Dutton on our behalf, asking the Health Minister *"what action the Government has taken to make consumers aware of the risks of undertaking non-accredited pathology tests"* and what the penalties are for practitioners or organisations providing these tests. FSM is grateful for the support and involvement of political figures committed to ensuring scientifically based health procedures. We hope for and expect a response from the Government on this matter soon.

FSM also wrote to the ACCC asking for a position statement on SCAM 'electro dermal screening (EDS) Devices', but have not yet received a response.

Pharmacy

Homeopathy & NHMRC

Following the release of the NHMRC draft information paper: Evidence on the effectiveness of homeopathy, FSM Pharmacy Facilitator, Ian Carr, challenged the sale of homeopathic goods in pharmacies. Carr was featured nationwide in newspapers including The Age. Following his article in MJA Insight, he was also featured in a number of online pharmacy journals including Pharmacy News and Postscript.com.au.



FSM has documented more than twenty pharmacies promoting homeopathy. FSM campaigns to convince all pharmacies to abandon the sale of homeopathic goods.

Australian Traditional Medicine Society (ATMS) / Pathology

Any member of the Australian Traditional Medicine Society (ATMS) using therapeutic goods which have not been accepted onto the Australian Register of Therapeutic Goods (ARTG) is guilty of professional misconduct – according to the ATMS' own [Code of Conduct](#) (section 3.12), which states *"The medicines and medical devices used by the practitioner must be in accordance with therapeutic goods law"*.

FSM wrote to the ATMS complaining about more than 70 ATMS registered practitioners. FSM included a report of images from their websites where pathology tests such as "live blood analysis", were promoted. This test, listed as invalid in the [FSM/RACP Pathology Recommendations](#), is not on the Australian Register of Therapeutic Goods (ARTG).

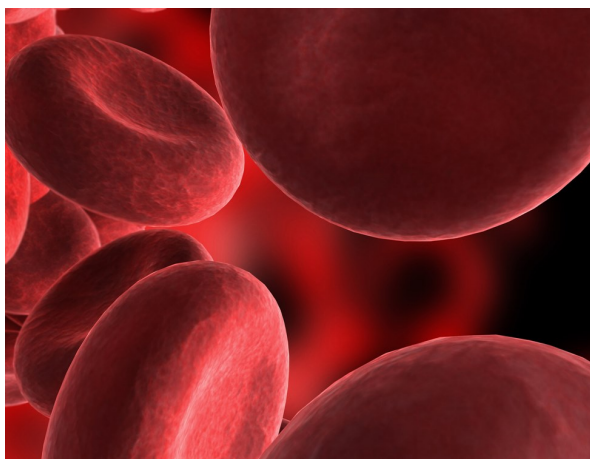
More than 300 websites listed on the [Natural Therapy Pages](#), plus hundreds more not included on this database, offer "live blood analysis". This is an *in vitro* diagnostic test with little scientific validity and, as such, came under the jurisdiction of the TGA in July 2010. At that time, the sponsors of existing devices were given four years to apply for a listing, until 30 June 2014.

FSM has asked the ATMS to indicate what relevant action is planned. FSM is awaiting a response.



Health World Ltd

Metagenics is a section of Queensland based complementary medicines sponsor, [Health World Ltd](#) (sponsors of Ethical Nutrients & Inner Health Plus) exclusively dedicated to practitioners. Metagenics offer a range of [unvalidated pathology tests](#) including "live blood analysis" (Hemaview). FSM has written asking them to withdraw their promotion of all unvalidated tests and to inform their



clientele once they have done so. They responded *"there is a transitional arrangement that allows for the use of unregistered devices until June 2015, after which all IVD's must be registered with the TGA. Use of Hemaview fits within this transitional arrangement and is currently allowed in Australia."* However, according to the Therapeutic Goods Administration website, the transitional period [expired on 1 July 2014](#).

FSM submissions

Feedback - Professional practice profile for pharmacists undertaking complex compounding

FSM supported the draft adding:

"Friends of Science in Medicine support all the changes to the regulations associated with Professional practice profile for pharmacists undertaking complex compounding proposed by the Pharmaceutical Board of Australia. If implemented and monitored, the changes will afford better consumer protection. Of importance is that it will be the enforcement regimen associated with these new changes."

Feedback - Guidelines on continuing professional development (Chiropractic)

FSM documented more than a hundred courses assessed by the Chiropractors' Association of Australia (CAA) which were either based on pseudo-science or made false or exaggerated claims of safety and efficacy.

In our submission, FSM challenged the ability of the CAA to assess Continuing Professional Development CPD courses and called upon the Chiropractic Board of Australia (CBA) to remove the Chiropractic Association of Australia (CAA) from their list of approved bodies for this task. FSM also requested that the CBA issue basic guidelines for their Continuing Professional Development (CPD) programs, specifically excluding teaching of non-evidence-based interventions such as, 'applied kinesiology', 'cranial therapy', the use of the 'activator' device and all paediatric oriented chiropractic courses.

FSM is aware that several courses have now been excluded from formal learning activities (FLAs): anti-vaccination and practice building.

FSM has documented more than a hundred and thirty practitioners promoting themselves as 'Chiropractic Neurologists'. These practitioners claim that this intervention is effective or can assist with a wide range of disorders including *"Vertigo, dizziness and balance problems, Tinnitus (ringing in the ears), Dyslexia & other learning disorders, Attention-deficit & Hyperactivity, Tremor & other movement disorders, Clumsi-*

ness, Sensory disturbances, Dystonia, Hearing or visual deficits, Communication difficulties, The effects of stroke or head trauma, and Other nervous system disorders". FSM has received no response to date.

Feedback - Guidelines on continuing professional development (Osteopathy)

In our submission, FSM requested that the Osteopathy Board of Australia (OsteoBA) issue basic guidelines for their Continuing Professional Development programs, specifically excluding teaching of non-evidence-based interventions such as 'craniosacral therapy' (Upledger), visceral manipulations (Barral) and all paediatrically oriented courses. FSM requested that these courses be audited. FSM has received no response to date.

Review of the National Registration and Accreditation Scheme for Health Professions

In our submission, FSM discussed the *"Discovery Of Serious Problems That We Thought AHPRA Would Help Us Resolve"* and asked *"Why Is AHPRA Unable To Address Problems Associated With The Unacceptable Practises Of Registrants?"*

FSM remains *"frustrated that no action has been taken after we documented hundreds of misleading advertisements by registered practitioners"* which clearly breach the National Law guidelines and highlighted that the Statutory Offences unit, who deal with complaints, is clearly under resourced and restricted by the unsatisfactory nature of its terms of reference. We also pointed out that *"the central issue with a number of the new AHPRA boards is that they include practitioners who have substantial vested interests in perpetuating the practices about which we and others are complaining."*

Our submission also included a 5 page summary of our extensive correspondence with AHPRA.



Publications & other media

'The Bitter Pill' - Australasian Science

Rachael Dunlop

Loretta Marron

[Balance Returning to Vaccination Information](#)

[Homeopathy Fails the Test – Again](#)

MJA Insight

Ian Carr

[Peddling homeopathy](#)

edzardernst.com

Edzard Ernst

[Does TCM cure cancer? A celebration of the irreproducible results](#)

[Magnetic bracelets: a paradise for charlatans](#)

I2P

Loretta Marron

[Annus horribilis for homeopathy?](#)

[Naturopaths in pharmacies? - whose "team" are they on?](#)

Crikey

Loretta Marron

[End of the road for homeopathy?](#)

[Are pharmacists thieves or therapists?](#)

The Conversation

Gustav Nossal

[Five Australian medical stories everyone should know](#)

Tim Crowe

[VIDEO: Are raw foods good for you?](#)

Mick Vagg

[Acupuncture, zombie fish and Humpty Dumpty](#)

Ian Musgrave

[Organic food is still not more nutritious than conventional food.](#)

Science-Based Medicine

Jann Bellamy

[Reiki: Fraudulent Misrepresentation](#)

Mark Crislip

[Moxibustion](#)

Scott Gavura

[Don't supplement users deserve consumer protection, too?](#)

David Gorski

["Integrative oncology": The Trojan horse that is quackademic medicine infiltrates American Society of Clinical Oncology \(ASCO\)](#)

Forbes

Prof Steven Salzberg

[Dr. House Was Right: Give Patients What They Need, Not What They Want](#)

Today Tonight Adelaide

FSM Vice President, [Prof Rob Morrison discusses the NHMRC findings on homeopathy.](#)

"The Amazing Meeting" 2013—Sunday Paper Presentation

FSM Exec Member, Joanne Benhamu presented ["Friends of Science in Medicine—Standing up for Science in Australia"](#).

Please let **FSM** know if you have published any relevant articles, been on radio or TV (with links, if possible), or any of your activities that support the objectives of Friends of Science in Medicine.